REMARKS

Claims 1-54 are pending in the present application. Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of February 7, 2007 the following actions were taken:

(1) Claims 1-4, 6, 7, and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yukiyoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");

(2) Claims 1-4 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");

(3) Claims 1-8, 19-21, 29-31, 38-40, 44-46, 48-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");

(4) Claims 1-9, 11, 19, 22-24, 28-31, 38-40, 44-46, and 48-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");

(5) Claims 1-4, 15-24, 26-31, 34-40, 43-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427");

(6) Claims 19 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper"); and

(7) Claims 1, 13-14, 32-33, 41-42, and 50-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi").

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-12, 15-24, 26-31, 34-40, 43-49, and 52-54 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied,* 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

Composition Claims 1 and 19

The Examiner has rejected claim 1 and/or 19 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, none of the references provide a hypoallergenic metal amino acid chelate composition as required by independent claims 1 and 19. In response to the Lumb and Nakamoto arguments made by the Applicant in prior office action responses, the Examiner has cited the Applicant's definition of "amino acid chelate"; alleging that the definition is broad enough to cover Lumb and Nakamoto. The Examiner has specifically stated that "any type of bonding between the metal and amino acid falls under the Applicant's definition . . ." However, the definition still requires for both traditional and modern chelates to form a heterocyclic ring. Such chelate formation is elaborated in Ashmead '424 and '427, references cited by the Examiner, which have been discussed in previous office action responses as well. Ultimately; regardless of ionic, covalent, or coordinate bonding; the

Applicant renews the arguments that Lumb and Nakamoto do not contain enough disclosure to enable someone to produce heterocyclic ring forming chelates. However, regardless of the reference, the Applicant would like to emphasize that the present invention requires a hypoallergenic metal amino acid chelate composition. The Applicant is not relying on just the structure of the chelate per se to show its distinction over the prior art, but rather the composition as a whole including other ingredients, fillers, impurities, etc. A chelate structure is not the same as a hypoallergenic composition that includes chelates. The Applicant has previously amended the claim set to remove any ambiguity as to this point of novelty in an effort to expedite the current prosecution.

As previously argued, even if Lumb and Nakamoto formed chelates, the Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427 references do not teach a hypoallergenic chelate composition. In fact, the references never mention hypoallergenic at all. The Applicant has claimed a specific narrow class of chelate-containing compositions. The chelate-containing compositions must contain hypoallergenic components that are substantially free of allergens. Because amino acid chelates must contain amino acids by definition, and because amino acids are typically prepared from protein hydrolysis, generally, many amino acids are not hypoallergenic, a point that the Examiner is ignoring.

The Examiner has restated that "'once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show the unobvious difference.'" See Office Action, page 3 (citing MPEP 2113). The Applicant has met this burden by its prior arguments, which are reiterated herein. Specifically, the Applicant contends that the composition is different than those found by the Examiner in Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. The Applicant has already discussed that Lumb and Nakamoto are not true chelates as defined by Ashmead '424 or '427. Even so, none of these compositions appear to be hypoallergenic and nothing in the references suggest that these compositions are hypoallergenic. The current independent claims specifically require that the chelates and the compositions that contain these chelates be substantially free of allergens. The previous compositions cited by the Examiner make no such claim and take no such steps to eliminate allergens from their respective compositions. Therefore, it is the Applicant's contention that absent a specific process or method of manufacturing that eliminates allergens, the cited compositions inherently contain impurities and allergens. The present hypoallergenic requirement significantly changes the composition of the product. Under the present application, the present amino acid compositions are

manufactured in such a manner that substantially eliminates allergens from the product. As such, the present compositions are chemically different than those disclosed in the prior art.

The Examiner has responded to the above hypoallergenic arguments by alleging that the compositions taught in the prior art are inherently hypoallergenic. The Examiner has relied on a portion of the Applicant's hypoallergenic definition, stating that "'hypoallergenic' refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects." Specifically, the Examiner has keyed on the phrase "where care has been taken." The Examiner states "that care has been taken in the formulation of metal amino acid chelates of the cited references" such that the chelates would be free of impurities including allergens. However, such allegations are without merit. The Examiner is assuming that "care has been taken" or, in other words, that the laboratory procedures would necessarily eliminate allergens. However, the prior art never discloses such teachings. The Examiner is alleging that any reference that discloses chelates safe for human consumption are necessarily hypoallergenic but the Examiner has not provided any reference that explicitly makes such a statement because such a statement is false. There are many human consumables available that do not claim to be hypoallergenic because they are not hypoallergenic. For example, baby formula is produced by many companies including Similac. Similac produces a regular formula, **Similac® Advance® Infant Formula**, and a hypoallergenic formula, **Similac® Alimentum® Hypoallergenic Formula**. Similac does not claim that every formula they produce is hypoallergenic, only one specific formula. For more information, please see http://welcomeaddition.com/. Ultimately, the Examiner is rejecting the pending claim set based on his assumptions, not what the prior art teaches. It must be recognized that most amino acids are prepared from protein hydrolysis, most of which would not be hypoallergenic.

The Examiner further alleges that the hypoallergenic evaluation recited in the method claims is performed in Lumb since Lumb uses a commercial source for the metal, J.T. Baker, and since Lumb recrystallized the amino acids several times. However, the J.T. Baker source never claims to be hypoallergenic and, regardless of the amino acid crystallization, the chelation process and final metal amino acid chelate product, if such a metal amino acid chelate ever formed (see above discussion), never claims to be hypoallergenic. The present invention requires an evaluation to ensure that all components are hypoallergenic as well as the final composition. The prior art does not provide such an evaluation.

As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

Method Claims 38 and 46

The Examiner has rejected claim 38 and 46 by several references; specifically, Hsu, Ashmead '424, and Ashmead '427. However, as previously argued, none of these references provide a method of preparing or administering a hypoallergenic metal amino acid chelate composition. The Applicant renews the arguments previously made with respect to these references above. Additionally, independent claims 38 and 46 specifically require an affirmative hypoallergenic determination. Each independent method claim requires a determination of the individual metal and amino acid components for chelation in forming the composition. The present specification is specific in defining the terms hypoallergenic, allergy, and allergen, so that no ambiguity arises as to the Applicant's methods and compositions. Specifically,

> "hypoallergenic" refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. . .
> "[a]llergy" refers to an acquired and abnormal immune response to a substance or moiety of a substance (allergen) that produces an altered bodily reaction. . .
> "allergen" refers to a substance that causes manifestations of allergy, such as a protein or antigen.

See page 8, lines 12-29. Elaborating on this affirmative hypoallergenic determination, the specification states that"[d]etermining whether a composition or its source is hypoallergenic indicates that some type of evaluative step be performed." See page 10, lines 21-28. None of the references provided by the Examiner refers to any such "evaluative step" as required by claims 38 and 46. Therefore, the Examiner has not provided a reference that requires every element of the method claims.

Additionally, the Applicant wishes to remind the Examiner that the product by process inquiry for composition patentability has no relation to the inquiry for the patentability of a method. The product is not required to be novel for patentability of the

method. The method is viewed independent of the product. With this in mind, the Examiner has not provided a reference that provides an affirmative step of hypoallergenic determination as part of the method in producing a metal amino acid chelate.

Furthermore, as previously argued, the Applicant wishes to point out the additional requirements of independent claim 48, which requires "identifying a subject susceptible to a type of allergic reaction" and "formulating a metal amino acid chelate" by selecting "amino acid source[s]" and "metal source[s] determined to be hypoallergenic with respect to the type of allergic reaction. . . ." See claim 48. The Applicant has previously posed the question: Where are these steps taught in the prior art? The Examiner has answered this question in the present office action stating "[i]t is the Examiner's position that any subject is susceptible to a type of allergic reaction and formulating a metal amino acid chelate by selecting amino acid sources and metal sources determined to be hypoallergenic with respect to the type of allergic reaction is explained in great detail above." The "great detail above" merely references the Examiner's position that the prior art allegedly teaches metal amino acid chelates free from impurities. There is no explanation as to how the references teach the above steps outside this one sentence statement. This response does not address the above question. The fact that a person may be allergic to any given substance is not a substitute for "identifying a subject susceptible to a type of allergic reaction." Likewise, as previously argued, the act of producing a metal amino acid chelate does not necessarily make the chelate hypoallergenic. The Applicant has a specific method for preparing the hypoallergenic metal amino acid chelates that are not taught in any of the references cited by the Examiner. Additionally, the above steps of "identifying a subject susceptible to a type of allergic reaction" and "formulating a metal amino acid chelate" by selecting "amino acid source[s]" and "metal source[s] determined to be hypoallergenic with respect to the type of allergic reaction. . ." are simply missing from all of the cited references. The Examiner has not explained how these steps are taught by the cited references but has instead simply made unsubstantiated allegations.

The Examiner has also stated that the preamble (using the term "hypoallergenic") is not given any patentable weight. However, independent claims 19, 38, and 46 all recite a "hypoallergenic metal amino acid chelate composition" in the body of the claim as well as references to metals and amino acids for making chelates that are hypoallergenic. Therefore, the term hypoallergenic should be given full patentable weight. Independent claim 1 does not recite hypoallergenic outside the preamble of the claim but still recites a composition that

is substantially free of allergens such that, upon administration, the composition does not produce a discernable adverse allergic reaction in the subject. As the prior art does not disclose such a composition, the Applicant contends that independent claim 1 is in condition for allowance as well claims 19, 38, and 46. Additionally, the Applicant submits that the dependent claims are also in condition for allowance.

Since the Examiner has not provided any single reference that provides each and every element of the present claims, the Applicant respectfully requests that current 102 rejections be withdrawn. As the Applicant has explained the novelty of the independent method claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 under 35 U.S.C. 103(a) as being unpatentable over several references.

Applicant does not deem it necessary to recited the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant, would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the two independent compositional claims is provided herein, as the Applicant asserts that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 as being obvious in view of various combinations of Hsu, Cooper, Ashmead '427, and Izumi. Specifically, as the Examiner has rejected two independent claims, 1 and 19, a discussion of these claims is provided.

The Examiner has combined two references, specifically Ashmead '427 and Izumi, to reject claims 1, 13-14, 32-33, 41-42, and 50-51. The Examiner has combined these references since Ashmead '427 does not teach "1) a method other than protein hydrolysis; 2) protein hydrolysis and wherein the protein used in the hydrolysis is hypoallergenic." See Office Action, page 11. The Examiner then states that Izumi teaches multiple methods including "enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods."

See Office Action, page 11. However, Izumi does not teach a hypoallergenic composition. Therefore, the combination of these two references would not successfully provide a hypoallergenic metal amino acid chelate composition as required by composition claim 1. In fact, the Examiner has not shown any such language in any reference in the current office action. The remaining rejected claims are dependent claims. The Applicant contends that every dependent claim also contains the hypoallergenic requirement through dependency. As such, the Applicant submits that these claims are also novel in view of the prior art.

The Examiner has alleged that "all that is require[d] to be hypoallergenic is that care be taken in the formulation and the compositions be prepared by oneself to insure purity [and] [o]ne of ordinary skill in the art is not sloppy in the making of compositions . . . ." However, such an argument does not fully appreciate a hypoallergenic composition. For example, one person may be able to consume or use commercially available foods/products with no adverse reaction where another person may not be able to consume or use the same foods/products even though the commercial supplier has arguably taken care in producing the foods/products. The fact is that there are different levels of quality and care needed to produce foods/products. The care to produce hypoallergenic foods/products is higher, as previously shown in the aforementioned baby formula example. The methods of the present invention ensure such a hypoallergenic composition; the methods of the prior art do not.

As the Examiner has not provided a combination of references that teach or suggest every element of the claimed invention and as the current combination of references would have no likelihood of success in producing the Applicant's invention, the Applicant respectfully requests that the corresponding 103 rejections be withdrawn.

The Examiner has combined two references, specifically Hsu and Cooper, to reject claims 19 and 25. As previously discussed, Hsu does not teach a hypoallergenic chelate composition. The Examiner has also identified this limitation, stating "Hsu et al. do not expressly disclose a composition wherein the formulation additive is a hypoallergenic flow control agent . . ." See Office Action, page 9. The Examiner then relies on Cooper as teaching the use of "the lubricant stearic acid." See Office Action, page 10. But where does Cooper teach a hypoallergenic flow control agent as identified by the Examiner? Cooper never states that the stearic acid is hypoallergenic or that any other materials or products are hypoallergenic. The Examiner has not shown any such language in any reference in the current office action, nor has the Examiner has provided a combination of references that teach or suggest every element of the claimed invention. As such, the combination of these

two references would not successfully provide a hypoallergenic chelate composition. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

CONCLUSION

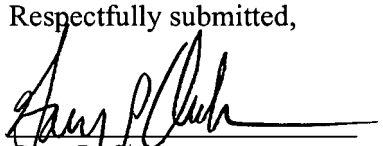
Because no reference has been shown that teaches a hypoallergenic chelate composition or a method using an affirmative hypoallergenic evaluative step, the Applicant respectfully asserts the Examiner has not satisfied the requirement for establishing a case of *prima facie* anticipation or of *prima facie* obviousness. Therefore, it is believed the present claim set should be allowable. Reconsideration is respectfully requested.

In view of the foregoing, the Applicant believes that claims 1-54 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson of this office, or in his absence, M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 7th day of May, 2007.

Respectfully submitted,



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